REMARKS

Reconsideration of the rejections set forth in the Office Action dated September 20, 2007, is respectfully requested. Claims 15-25 remain pending. The drawings have been corrected as suggested by the Examiner and therefore the objection to the drawings should be withdrawn. The priority claim has been corrected as suggested by the Examiner and therefore the objection to the priority claim should be withdrawn.

The Art Rejections

Claims 15-25 were rejected under 35 U.S.C. § 103 as allegedly unpatentable over Yuan in view of Grooms and Cauthen. This rejection should be withdrawn for the following reasons.

Claim 15 requires use of a graft comprising first, second, and third segments, "wherein the first and third segments comprise vertebral bone tissue and the second segment comprises annulus fibrosis tissue." None of the cited references teach or suggest use of a graft having these claimed features. The Examiner, however, takes the position that starting from Yuan, one might have ignored the teaching to use metallic screws and instead used bone in place of the metallic screws, and then further ignored Yuan's teaching to use a mesh as the second segment and instead used annulus fibrosis tissue. The cited references would not yield the claimed subject matter even if combined as suggested and in fact actually teach away from the claimed method.

The Examiner takes the position that Cauthen suggests to use annulus fibrosis tissue in place of the mesh in Yuan. Not so. Cauthen teaches to use allograft fascia rather than annulus fibrosis tissue to repair a defect. Fascia does not have the same structure or biomechanical characteristics as annulus fibrosis tissue. Fascia is weaker than annulus fibrosis tissue, does not have multiple lamellae with fibers that course in alternating directions (+/- 60 degree to the

longitudinal axis of the spine), is less stiff than annulus fibrosis tissue, and is substantially thinner that annulus fibrosis tissue. Applicant's invention requires pieces of bone that are naturally connected to both ends of the annulus fibrosis tissue. Such connections cannot be created with separate pieces of bone and fascia. The natural connection is much stronger than any manufactured connection that can be created. Moreover, Cauthen fastens his fascia to the annulus fibrosis, not to the vertebrae as required by the claimed invention. Thus, even if the asserted combination of references were proper (which it is not because Yuan and Grooms teach away as explained below), the combination of references would not produce the claimed invention but would instead result in fascia with a weak connection to bone that would be ineffective for annulus fibrosis tissue reconstruction.

Further, both Yuan and Grooms relate to spinal fixation and fusion. In order to explain the significance of this distinction and why one skilled in the art would rule out as inapplicable the references cited by the Examiner, Applicant submits herewith the Declaration of Bret Ferree, M.D., a Board Certified orthopedic surgeon who specializes in spinal surgery. He has performed over 1,500 surgeries to repair disc herniations and is therefore familiar with the types of devices that can and cannot be used to reconstruct in the anulus fibrosus. Both spinal fixation and fusion require a bone graft or cage to be placed into the disc space. Ferree Decl., ¶ 4. Annulus fibrosis tissue is known to be thick and, if used in a three-segment implant as required by claim 15, would result in implanted annulus fibrosis tissue being placed "adjacent the diseased annulus fibrosis. (See claim 15.)" Ferree Decl., ¶ 5. Because of this arrangement, the thick annulus fibrosis tissue would significantly reduce the size of the cage or bone graft material that can be placed into the disc space. Ferree Decl., ¶ 5. Thus, one skilled in the art would actually seek to avoid use of annulus fibrosis tissue as the second segment for purposes of spinal fusion and

fixation. See Ferree Decl., ¶ 5. Yuan and Grooms therefore teach away from the claimed invention.

Moreover, Applicant's invention represents a significant innovation in the field of annulus fibrosis reconstruction. Removal of a segment of annulus fibrosis to insert an interbody fusion implant, in the manner taught by Yuan and Grooms, allows excessive spinal movement. Removal of or injury to spinal ligaments, such as the anterior longitudinal ligament (ALL), in the manner taught by Yuan and Grooms also leads to excessive spinal movement. For example, removal of a portion of the anterior annulus fibrosis and ALL to insert an interbody implant, as taught by Yuan and Grooms, allows excessive spinal extension and axial rotation. Such excessive spinal motion decreases the chances of fusion between the vertebrae. Applicant's invention reconstructs the damaged tissue, including the annulus fibrosis and ALL, restoring the function of such injured tissues thus preventing excessive spinal motion.

Applicant's bone and annulus fibrosis tissue device is a unique spinal implant material. First, bone is the only tissue in the body that heals without scar tissue. Scar tissue is generally weaker than native tissue and does not have the same biomechanical properties as native tissue. The bone or bone substitute of Applicant's device heals directly to the area of the vertebrae where bone tissue was removed. Second, the soft annulus fibrosis tissue of Applicant's device has the proper length to extend across an intra vertebral disc (with bone pieces at either end) and has the biomechanical properties of the native spinal tissues they replace.

Third, the annulus fibrosis is a unique structure. The annulus fibrosis is made of ten to twenty collagen fiber lamellae, with successive lamellae oriented in alternating directions. Fibrocytes grow into the annulus fibrosis tissues of the second segment. The annulus fibrosis tissue causes the fibrocytes to assume the unique orientation of the annulus fibrosis. Yuan's one

segment device does not direct osteocytes to grow into a first and third portion of the device and does not direct fibrocytes to grow into the central portion of the device. Furthermore, fibrocytes that grow into Yuan's device will not assume the unique orientation of fibrocytes of annulus fibrosis tissue. When the patient's fibrocytes grow into the annulus fibrosis scaffold, the fibrocytes revitalize the annulus fibrosis tissue and connect the donor annulus fibrosis to the patient's annulus fibrosis. The donor tissue guides the fibrocytes to form annulus fibrosis tissue (multiple lamellae, 60 degree angles, alternating orientation). The unique orientation of annulus fibrosis tissue gives it unique biomechanical properties.

Finally, applicant's invention also restores normal kinematics following injury to the annulus fibrosis and ALL during insertion of motion preserving interbody devices such as total disc replacements or nucleus replacements. Excessive spinal motion following insertion of motion preserving implants leads to degeneration of the facet joints and thus may cause low back pain.

Claim 15 is therefore patentably distinct from the cited references. Each of claims 16-25 is dependent on claim 15. These dependent claims are therefore patentably distinct from the cited references for the same reasons applicable to claim 15.

Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicant's undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,
O'MELVENY & MYERS LLP

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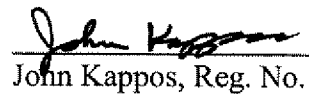
By: 
John Kappos, Reg. No. 37,861
Attorneys for Applicants

O'Melveny & Myers LLP
610 Newport Center Drive, Suite 1700
Newport Beach, CA 92660-6429
(949) 760-9600